REMARKS

Claims 1 and 32-69 are pending; and of these, claims 1 and 53 have been amended. Claims 2-31 have been previously cancelled. Reconsideration of the instant application in view of this Paper is respectfully requested.

The Examiner has (1) rejected claims 1, 34, 38-40, 46-58, 66, 68 and 69 under 35 U.S.C. 102(b) as being anticipated by Gotfried (U.S. Pat. No. 5,429,641); (2) rejected claims 32, 33, 59 and 60 under 35 U.S.C. 103(a) as being unpatentable over Gotfried; (3) rejected claims 35, 41-44, 61-64 and 67 under Section 103(a) as being unpatentable over Gotfried in view of Nelson (U.S. Pat. No. 6,562,042); (4) rejected claims 36 and 37 under Section 103(a) as being unpatentable over Gotfried in view of Lower (U.S. Pat. No. 4,612,920); and (5) rejected claims 45 and 65 under Section 103(a) as being unpatentable over Gotfried in view of Nelson and further in view of Lee et al. (U.S. Pat. No. 3,939,498). Applicant has amended Applicant's independent claims 1 and 53, and with respect to these claims, as amended, and their respective dependent claims, the Examiner's rejections are respectfully traversed.

Applicant has amended independent claim 1 to recite Applicant's system for minimally invasive treatment of a fracture of a bone, comprsing: an osteosynthetic plate including a support section positionable with a support surface against said bone adjacent to the fracture and a fastening section for fixing said osteosynthetic plate to said bone, a fixation element for fixing in a fragment of said bone that was dislodged by the fracture, and comprising a shaft portion, a guide element including

a first connecting section—via which said guide element is fastenable to said osteosynthetic plate—and—a second connecting section—for guiding said fixation element, said support section of said osteosynthetic plate—having at least—first and second recesses, said fixation element—and said guide element—being insertable into said bone—through said first recess, said second connecting section providing a seat—in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto, and an anti-rotation screw for substantially preventing rotation of the bone fragment, and comprising a head portion for insertion through said second recess of said support section and into said dislodged bone fragment, said head portion and said second recess being threaded for mating engagement therebetween. Applicant's independent claim 53 has been similarly amended.

The constructions recited in Applicant's independent claims 1 and 53 are not taught or suggested by Gotfried, Nelson, or Lower, either when taken alone or in combination. More particularly, there is no teaching or suggestion of either Applicant's featured second connecting section providing a seat in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto, or Applicant's featured anti-rotation screw for substantially preventing rotation of the bone fragment, and comprising a head portion for insertion through said second recess of said support section and into said dislodged bone fragment, said head portion and said second recess being threaded for mating

engagement therebetween. Accordingly, none of the references offers the advantages of Applicant's construction, as discussed at least at pages 6-7 and 8 of Applicant's specification, and namely (1) the ability to allow for settling that occurs at a bone fissure during the healing process in view of Applicant's recited second connecting section providing a seat in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto, and (2) the ability to reliably prevent rotational movement of bone fragment in view of Applicant's recited arrangement of Applicant's (a) osteosynthetic plate, and its support section having first and second recesses, (b) guide element and (c) fixation element, together with (d) Applicant's recited anti-rotation screw for substantially preventing rotation of the bone fragment, and comprising a head portion for insertion through said second recess of said support section and into said dislodged bone fragment, said head portion and said second recess being threaded for mating engagement therebetween.

In the Examiner's rejection, the Examiner equates the screw II of Gotfried to Applicant's fixation element, and its sleeve III to Applicant's guide element. This comparison is improper.

First, such comparison is improper because the screw II and sleeve III of Gotfried lack the positional arrangement and consequent positional accuracy and adjustment associated with Applicant's guiding and fixation elements. As described at column 6, line 33 - column 7, line11 of Gotfried, its screw II and sleeve III are

configured as a "screw-and-sleeve" <u>assembly</u>, and are thus only positionable through Gotfried's connector plate I as a complete unit, both at the time of insertion and after completion thereof. This is in contrast to Applicant's recited construction. Initially, Applicant's "guide element is fastenable" to Applicant's osteosynthetic plate. As such, Applicant's guide element is positionable to act, along with Applicant's osteosynthetic plate, to <u>subsequently then</u> guide Applicant's fixation element during both at the time of insertion within the intended bone structure and <u>throughout</u> the healing process. Page 25, lines 12-20 of Applicant's specification. In this way, Applicant's guide element cooperates with Applicant's fixation element to increase the positional accuracy of such fixation element. Nowhere in Gotfried is there any teaching or suggestion that its sleeve III acts in any way which is similar to Applicant's recited system. Accordingly, Gotfried fails to teach or suggest Applicant's recited "guide element," and thus is unable to provide the positional accuracy afforded by its cooperation with Applicant's recited fixation element.

Second, Gotfried fails to teach or suggest Applicant's guide element and its "second connecting section providing a seat in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto." As stated at column 4, lines 59-68, Gotfried's "... screw [II] is slidably, but tightly inserted into ... sleeve [III] The inner end of the sleeve is inwardly crimped ... thereby preventing the screw from sliding out of the sleeve." Though this description is provided, there is in no way any teaching or suggestion of

Applicant's recited "seat," in which Applicant's "fixation element is free from tilting therein" throughout the bone-healing process. Instead, the aforementioned description merely suggests that Gotfried's screw II is initially inserted within its sleeve III in a "tight" manner, and is prevented from disengaging from the sleeve III by virtue of the crimped ends of the sleeve at 18 thereof. There is nothing which teaches or suggests that any portion of Gotfried's screw II is tiltably restricted in any way subsequent to its insertion within its sleeve III. Further, Gotfried fails to teach or suggest at least a second aspect of Applicant's recited guide element and its provided "seat", in which Applicant's fixation element is also "moveable axially with respect (to said guide element)" throughout the bone-healing process. As described at column 6, line 33 - column 7, line 11, Gotfried's screw II is pulled into its associated sleeve III by means of its retracting device VI to set a fractured bone portion in place. Given this, Gotfried accomplishes healing of a bone fracture by pulling the fractured portion toward a non-fractured portion, and in doing so in the manner described, establishes a rigid connection with the fractured bone portion since screw II is not intended to move axially within sleeve III once it is set. This is directly opposite to Applicant's intended system in which Applicant's fixation element is "moveable axially" relative to Applicant's recited guide element throughout the bone-healing process. As such, Applicant's system provides a nonrigid connection with a fractured bone portion to allow for settling that occurs at the bone fissure during healing. Page 6, line 20 - Page 7, line 5 of Applicant's

specification. Accordingly, Gotfried fails to teach or suggest Applicant's guide element, and more specifically, its featured "second connecting section providing a seat in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto."

Third, Gotfried fails to teach or suggest Applicant's recited "anti-rotation screw for substantially preventing rotation of the bone fragment, and comprising a head portion for insertion through said second recess of said support section and into said dislodged bone fragment, said head portion and said second recess being threaded for mating engagement therebetween."

In the Examiner's rejection, the Examiner asserts that one of the pair of long screws II shown in Gotfried equates to Applicant's above-recited anti-rotation screw. Such assertion is misguided for at least two reasons. First, neither of the long screws II in Gotfried comprise a head portion which is <u>itself</u> threaded. Rather, all that is mentioned in this regard is that Gotfried's sleeve III is threaded and is screwed into its connector plate I. Column 6, lines 52-54. Second, providing threads on the head portion of either one of Gotfried's long screws II would interfere with its intended arrangement within sleeve III, and the ability for Gotfried's construction to accomplish its intended process for bone healing.

Nelson, Lower and Lee et al. fail to teach or suggest anything, either when taken alone or in combination with Gotfried, which addresses the inadequacies of Gotfried.

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Thus, in view of the above, it is believed that the claims now patentably distinguish over Gotfried, Nelson and Lower, either when taken alone or in combination.

No fee is believed due. If there is any fee due the USPTO is hereby authorized to charge such fee to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,

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